

FDA FOOD SAFETY MODERNIZATION ACT



FSMA—What You Need To Know An online informational session

Module III. Foreign Supplier Verification Program

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Important Notice

- Because sections were abbreviated for this presentation, the information provided is only an overview and should not be relied upon as a substitute for reading the final rule, or obtaining legal advice, or as a summary of all regulatory requirements.
- Every company must conduct its own detailed review of the final rule.



MODULE III. FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

Final Rule published November 27, 2015

FSMA Sec. 301 requires importers to have FSVP and FDA to issue regulations



What is a FSVP?

- Program for covered importers requiring them
 - To verify that their foreign suppliers are producing food using processes and procedures that provide the same level of public health protection as the preventive controls or produce safety regulations
 - To ensure that the supplier's food is not adulterated or misbranded (for allergens).



Key Principles of FSVP Rule

- Requires importers to share responsibility for ensuring safety of imported food
- Risk-based (according to types of hazards, importers, and suppliers)
- Flexibility in meeting requirements (assessing activities conducted by others)
- Alignment with supply-chain PC provisions



Qualified Individuals

- Must use a *qualified individual* to perform all required FSVP tasks
 - Must have education, training, or experience (or combination thereof) necessary to perform the activity
 - Must be able to read and understand the language of any records reviewed in performing an activity



FSVP

- Who must comply?
 - Importer
 - U.S. owner or consignee of a food for import into the U.S. at time of entry into the U.S.
 - OR (if no U.S. owner or consignee) the U.S. agency or representative of the foreign owner or consignee at the time of product entry into the U.S., as confirmed in a signed statement of consent
 - Exemptions (see Final Rule)
 - Final Rule

<https://www.federalregister.gov/documents/2015/11/27/2015-28158/foreign-supplier-verification-programs-for-importers-of-food-for-humans-and-animals> (accessed November 24, 2017)



What activities does the FSVP include?

- Hazard analysis: determining if *known or reasonably foreseeable hazards* for each food require a PC
 - Biological, chemical (including radiological), and physical hazards
 - Naturally occurring, unintentionally added, or intentionally introduced for economic gain
 - May assess another's hazard analysis

What activities does the FSVP include? (cont'd)

- Evaluation of food risk
- Evaluation of supplier performance by the importer
- Supplier verification (e.g., auditing, sampling and testing, record review)
- Corrective actions
- Recordkeeping



Requirements for Special Circumstances

- The food cannot be consumed without application of control (e.g., coffee beans).
- Hazard controlled by importer's customer or subsequent entity in US distribution.
 - Disclosure statement
 - Written assurance
 - Other system to ensure control of hazard at subsequent distribution step

Exemptions and Modified Standards (FSVP)

- Foreign dietary supplement facilities or packaging meets specifications under GMP
 - Other dietary supplements (including finished supplements)
- Juice, fish and fishery products under Seafood HACCP
- LACF but only for microbiological hazards
- Alcoholic beverages and ingredients (when importer uses them to make alcoholic beverages)



Exemptions and Modified Standards (FSVP) (cont'd)

- Food for research or evaluation
- Food for personal consumption
- Food imported for processing and future export
- Food transshipped through the U.S.
- “U.S. food returned”
- Meat, poultry, and egg products subject to USDA regulation at time of importation



Guidance for Industry

- Supply-chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM583490.pdf> (accessed November 24, 2017)



Compliance Dates FSVP after November 27, 2015

Food Facility	Compliance Dates
All importers	18 months
Supplier subject to Human PC or Produce Safety Rule	6 months after foreign supplier is required to comply with FSMA or 18 months whichever is later
Receiving facility: NOT a small or very small business and supplier is not subject to Human PC or Produce Safety Rule	18 months
Importer that is also a manufacturer or a processor	Date by which it is required to comply
Supply-chain program provisions	Dates vary depending on: <ul style="list-style-type: none"> • Size of receiving facility • Date by which receiving facility's supplier is required to comply



If You Have A Question, Ask:

- FSPCA Technical Assistance Network

http://www.iit.edu/ifsh/alliance/resources/technical_assistance_network_inquiry_form.shtml

- FDA Technical Assistance Network

<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM467582.pdf>



END OF MODULE III

